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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/889,182

01/10/2002

Frank Breitling

4121-126

8533

23448

7590

05/02/2007

INTELLECTUAL PROPERTY / TECHNOLOGY LAW

PO BOX 14329

RESEARCH TRIANGLE PARK, NC 27709

EXAMINER

GRUN, JAMES LESLIE

ART UNIT

PAPER NUMBER

1641

MAIL DATE

DELIVERY MODE

05/02/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/889,182

Applicant(s)

BREITLING ET AL.

Examiner

James L. Grun

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1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 21-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 21-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 November 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09 February 2007 has been entered. Claims 25 and 26 are newly added. Claims 15-20 have been cancelled. Claims 1-14 and 21-26 remain in the case.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The specification is objected to and claims 1-14 and 21-26 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons of record set forth in the prior rejection of the similar subject matter of claims 1-14 and 21-24, that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, and which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As set forth, even if one assumes retention of the antibody binding protein in the hybrid cells, which is not predictable for the reasons of record, one would not be assured of the ability to select the desired producer cell(s) from the population because, absent further guidance from applicant, one would be unable to identify and specifically separate the secreting cell(s)

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from a population of cells which are all (or, if the above assumption is not made, partly) capable of binding the secreted product.

Applicant's arguments filed 09 February 2007 and 09 November 2006 have been fully considered (or reconsidered) but they are not deemed to be persuasive. Applicant's arguments were not found persuasive for the extensive reasons of record regarding the unpredictability of retaining both the binding protein and antibody production in a particular hybridoma, the unpredictability of identifying and separating a secreting cell from a binding cell, and/or the unpredictability of identifying and separating a secreting and binding cell from a binding cell.

Notwithstanding applicant's assumptions to the contrary, the examiner did indeed intend to make the observation that protein G binds goat IgG, the implication being that the use of such an immunoglobulin as a labeled reagent could confuse the assay and not support the identification of surface mouse immunoglobulins if the labeled goat IgG reagent was being bound by a binding cell having protein G on its surface (another example of antibody uptake by undesired non-secreting cells having antibody binding molecules expressed on their surface).

The examiner questioned applicant's prior unsubstantiated and unsupported assertion that the antibody producing cells express antibodies on their surfaces which are pre-bound to the understood "large amount" of antibody binding proteins intracellularly, trapping the antibodies on the expressing cells, and thus that the producing cells can be distinguished from the non-producing cells by fluorescence analysis. In this regard, applicant urges that the claims do not require trapping of all antibodies, only enough antibodies. This is not found persuasive for the reasons of record because the issue is not if the claims recite trapping of all antibodies, as argued

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by applicant, the issue is again the secretion of excess antibodies by secreting cells which are bound by binding cells which are not the secreting cells in the unseparated cell population.

The specification is objected to and claims 21-24, are rejected under 35 U.S.C. § 112, first paragraph, for the reasons of record that the instant claims contain subject matter which was not described in the specification, as originally filed, in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the invention as is now claimed.

Applicant's arguments filed 09 February 2007 and 09 November 2006 have been fully considered (or reconsidered) but they are not deemed to be persuasive. Applicant's arguments were not found persuasive for the extensive reasons of record regarding the lack of written description and guidance for prior selection of B-lymphocytes for fusion.

Claims 25 and 26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification, as originally filed, does not provide support for the invention as is now claimed. It is not clear that the possibility of using the method as claimed for the purpose as claimed was explicitly or implicitly originally contemplated as part of applicant's invention and such possibility of use does not satisfy the written description requirements of 35 U.S.C. § 112, first paragraph. Note that a description which renders obvious a claimed invention is not

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sufficient to satisfy the written description requirement. Moreover, claims which lack the critical or essential element to the practice of the invention, i.e. inserting a coding vector for expression of an antibody binding protein in the myeloma cell, but which is not included in the claim(s), are not supported by the written description. Applicant is requested to direct the Examiner's attention to specific passages where support for these newly recited limitations can be found in the specification as filed or is required to delete the new matter.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25 and 26 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Miltenyi et al. (WO 94/09117).

Miltenyi et al. teach direct selection of cells which secrete a product, including hybridomas, by labeling the producer cells in a population with the secreted product therefrom and detecting the products on the cell surface (see e.g. pages 22-23). The cells are coupled at their surface with a specific binding partner for capturing the product, including anchoring the binding partner in or on the cell membrane. The capture binding partner can be anti-class antibodies such as anti-IgM antibodies (see e.g. pages 24 and 32-35). The reference contemplates isolating cells producing a product from encoding DNA introduced into the cells (see e.g. pages 24-25). The reference relies on anchoring the specific binding partner by chemical means.

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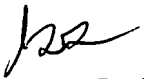
Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (571) 272-0823.

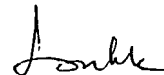
The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



James L. Grun, Ph.D.
April 27, 2007



LONG V. LE 04/27/07
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600